For FDA:

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IX. Acceptance By Both Parties To The Agreement

FOR THE DEPARTMENT OF VETERANS AFFAIRS, VHA	FOR HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION
By (Signature) Robert M Kolodner	By (Signature) Janet Woodcock MD
Name Robert M. Kolodner, M.D.	Name
Title Acting VHA Chief Health Informatics Officer	Title Acting Deputy Commissioner for Operations
Date 6/13/2005	Date 6/28/05

[FR Doc. 05–18513 Filed 9–16–05; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0340]

Draft Guidance for Industry on Acne Vulgaris: Developing Drugs for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Acne Vulgaris: Developing Drugs for Treatment.'' This document has been developed to provide guidance on the development of drug products for the treatment of acne vulgaris other than nodulocystic acne.

DATES: Submit written or electronic comments on the draft guidance by December 19, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Frank Cross, Center for Drug Evaluation and Research (HFD–540), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301–827–2020.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Acne Vulgaris: Developing Drugs for Treatment.'' This document has been developed to provide guidance on the development of drug products for the treatment of acne vulgaris other than nodulocystic acne. The information presented may help applicants plan clinical studies, design clinical protocols, implement and appropriately monitor the conduct of clinical trials, collect relevant data for analysis, and perform appropriate types of analyses of study data.

The recommendations in the draft guidance are based on careful assessment of important issues raised in the review of clinical trials for acne vulgaris. These recommendations represent the agency's current thinking regarding design of clinical trials intended to support the approval of drug products for the treatment of acne vulgaris. Applicants are encouraged to discuss development plans with the agency review division before embarking on a study, to ensure that the

clinical trial design and analysis plan meet defined objectives.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance has been approved under OMB control number 0910–0001 (expires May 31, 2008).

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: September 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–18512 Filed 9–16–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0018] (formerly 02D–0018)

Guidance for Industry on the Collection of Race and Ethnicity Data in Clinical Trials; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Collection of Race and Ethnicity Data in Clinical Trials.'' This guidance provides recommendations on a standardized approach for collecting and reporting race and ethnicity information in clinical trials conducted in the United States and abroad for certain FDA regulated products. This document provides guidance on meeting the requirements in the 1998 final rule on Investigational New Drug Applications and New Drug Applications (Demographic Rule) (63 FR 6854, February 11, 1998).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Katherine Hollinger, Office of Women's Health, Office of Science and Health Communication (HF–8), 5600 Fishers Lane, Rockville, MD 20857, 301–827–0935, or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), 1401 Rockville Pike, Rockville, MD 20852, 301–827–6210, or

Investigational Device Exemption Staff (HFV–403), Center for Devices and Radiological Health, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Collection of Race and Ethnicity Data in Clinical Trials.'' A draft of this guidance was issued on January 30, 2003 (68 FR 4788). Based on comments received on the draft and the refinement of agency thinking on this topic, FDA has revised the draft guidance and is now issuing a guidance. This guidance is intended to assist sponsors in the collection of race and ethnicity information in clinical trials conducted in the United States and abroad for certain FDA regulated products using a standardized approach. The standardized approach was developed by the Office of Management and Budget (OMB). FDA believes that the use of the OMB approach will facilitate comparisons across clinical studies analyzed by FDA and data collected by other Federal agencies. Although FDA has long requested the racial and ethnic ancestral origins of subjects in certain clinical trials, the agency is now making recommendations on the methods and categories to use when collecting and reporting data. The Department of Health and Human Services (HHS) issued a 1999 report entitled ''Improving the Collection and Use of Racial and Ethnic Data in HHS,'' in which HHS announced the adoption of OMB Directive 15 as part of its policy on collecting and reporting data on racial and ethnic ancestral origins.

FDA received several comments in response to the January 2003 draft guidance and has made some clarifying changes in the final version of the guidance. Specifically, we have:

1. Added reference to 21 CFR 314.50(d)(5)(v) to include studies for efficacy.

2. Clarified the traceability/mapping between more granular characterizations for racial and ethnic ancestral origins: ''When more detailed characterizations are desired, the use of Race and Ethnicity vocabulary tables located within Health Level Seven's Reference Information Model Structural Vocabulary Tables is recommended. These tables provide the five and two OMB characterizations traceable to more detailed characterizations and concept